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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,601	11/15/2000	Poonam Agarwal	FORS-04603	9798

23535 7590 05/23/2003

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EXAMINER

HASHEMI, SHAR S

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 05/23/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/713,601

Applicant(s)

AGARWAL ET AL.

Examiner

Shar Hashemi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/24/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Applicant's Response (filed 18 February 2003) was received and entered as Paper No. 13. Claim 4 was canceled. The claims pending in this application are **Claim(s) 1-3 and 5-11**. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Response to Arguments

2. Applicant's state the following: 1. US 5,994,069 is "not prior art over the pending patent." 2. "a claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference." Applicant's arguments have been fully considered but they are not persuasive because the Applicant has failed to point out which elements were not described in the cited '069 Patent. The Applicant is directed to the rejections set forth below.

Sequence Rules

3. This application does comply with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

Claim Rejections - 35 USC § 112

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4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The active steps in claim 1 render claims 1-3 and 5-6 confusing because the preamble recites a method for detecting a target sequence while the active steps do not recite detecting a target sequence. Furthermore, step (c) of claim 1 provides no nexus to the preamble.

B) Claim 5 recites the limitation "said wherein." There is insufficient antecedent basis for this limitation in the claim. Amending the claim to delete "said" from the phrase "said wherein" would obviate the rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C.

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122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1-3 and 5-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Hall et al (US 5, 994, 069 November 30, 1999).

Hall et al in US 5, 994, 069 teach a method and kit for detecting a target sequence comprise utilizing a sample containing target sequence (col. 1, lines 25-39; col. 7, lines 16-67), utilizing oligonucleotides having the ability to form an invasive cleavage structure in the presence of target sequence (col. 7, lines 21-24), utilizing an agent to detect the presence of an invasive cleavage structure (col. 10, lines 15-34), exposing the sample to the oligonucleotides and agent (col. 8, lines 25-39). They further teach that in the exposing step the invasive cleavage structure is formed between the target sequence and oligonucleotides when the target sequence is present in the sample and the invasive cleavage structure is cleaved by the cleavage agent to form a cleavage product (col. 8, lines 8, lines 25-39). They teach a step of detecting the cleavage product (col. 8, lines 38-67). They teach the target sequence comprise a first and second region where the second region is downstream and contiguous to the first region (col. 7, lines 23-29). They also teach oligonucleotides comprise first and second oligonucleotides where a portion of the first oligonucleotide is complementary to the first portion of the target sequence and where the second oligonucleotide has a 3' and 5' portion where the 5' portion is complementary to the second region of the target sequence (col.12, line 1-51). They teach the target sequence is human cytomegalovirus viral DNA (col. 13, lines 42-67; col. 168, lines 50-67).

7. Claims 1-3 and 5-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Dahlberg et al (US 5,837,450 November 17, 1998).

Dahlberg et al teach a method and kit for detecting a target sequence comprising the limitations set forth in claims 1-3 and 5-11 (see whole document, especially col. 8, lines 20-62; col. 12, lines 13-54; col. 16, lines 34-67; col. 22, lines 18-38; col. 43, see example 5).

CONCLUSION

8. Claims **1-3 and 5-11** are rejected for the reasons set forth above.

9. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal. If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

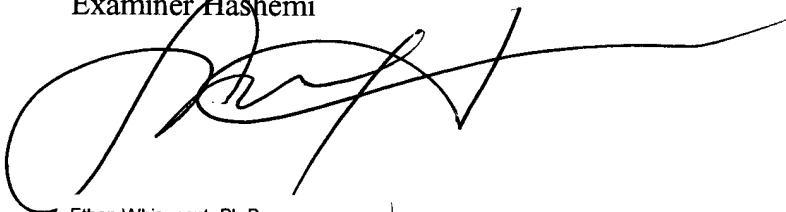
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A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840. The examiner can normally be reached Monday-Friday from 8:00AM – 5:00PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

The fax number for this examiner is (703) 746-9038. Before faxing any papers, please inform the examiner to avoid lost papers. Please note the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist, Tracey Johnson, whose telephone number is (703) 305-2982.

Examiner Hashemi



Ethan Whisenant, Ph.D.
Primary Examiner
Art Unit 1634

